K123396

Section 5.0: 510(k) Summary

JAN 10 2013

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Manufacturer	Thermoplastic Comfort Systems, Inc.
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Telephone	562-426-2970
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Contact at TCS	Marilin Posca President
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Device Name and Classification

Trade name/Product Name	i.flex by TCS
Common/Usual Name	Dental resin
Classification Name	Resin, Denture, Relining, Repairing, Rebasing
Classification Panel	Dental
Product Code	EBI
Regulation Number	21 CFR 872.3760
Class	II

Predicate Device

Manufacturer	Cosmetic Dental Materials, Inc. (The Myerson Company, Ltd.)
Device Name	DuraFlex
510(k) Number	K063626

Device Description

i.flex by TCS is an injection moldable, flexible, thermoplastic resin provided with trace amounts of colorant added to produce shades of pink. The dental resin is packaged in individual use cartridges or in bulk.

i.flex by TCS is used for fabricating removable dental prosthetic appliances such as full and partial dentures, occlusal splints and night guards.

Indications for Use

i.flex by TCS is a thermoplastic resin used for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.

Substantial Equivalence

The i.flex by TCS device is substantially equivalent to the DuraFlex dental resin (K063626).

The claim of substantial equivalence for the i.flex by TCS is based on intended use, technology and performance specifications. Both the i.flex by TCS and the predicate device are composed of a thermoplastic, ethylene propylene copolymer identified by its CAS registration number 9010-79-1. Both devices are supplied in a natural or clear state as well as in shades of pink. Both materials are supplied in cartridges which are heated to allow for the injection molding of the resin for the fabrication of dental prostheses.

Biocompatibility

Biocompatibility testing of the i.flex by TCS material was conducted in accordance with ISO standards to demonstrate the safety of the device.

The following biocompatibility tests were conducted:

1. Cytotoxicity: Agar overlay per ISO 10993-5:2009
2. Cytotoxicity: MEM elution per ISO 10993-5:2009
3. Delayed-type hypersensitivity (sensitization): Magnusson-Klingman Method per ISO 10993-10:2010
4. Irritation: Intracutaneous Toxicity (ISO) per ISO 10993-10:2010
5. Genotoxicity: Ames Test per ISO 10993-3:2009

The test results confirm that the i.flex by TCS device is non-cytotoxic, non-sensitizing, non-irritating and non-mutagenic.

Performance Testing to Recognized Standards

The i.flex by TCS device was tested to the applicable clauses of the recognized consensus standards for dental materials listed below.

1. ANSI/ADA Specification No. 12:2002/ISO 1567:1999 - Denture Base Polymers
2. ANSI/ADA Specification No. 80:2001/ISO 7491:2000 - Dental Materials – Determination of Color Stability

The study results demonstrate that the i.flex by TCS meets the performance criteria specified in the recognized standards cited or for the performance of the predicate device, DuraFlex, confirming the substantial equivalence of the i.flex by TCS to the predicate device.

Summary of Performance Testing – Conclusion

The results of all testing demonstrate that the i.flex by TCS device does not raise any new significant issues of safety, effectiveness or performance of the device when compared to the existing predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 10, 2013

Ms. Marilin Posca
President
Thermoplastic Comfort Systems, Incorporated
2619 Lime Avenue
SIGNAL HILL CA 90755

Re: K123396
Trade/Device Name: I.Flex by TCS
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Codes: EBI, MQC
Dated: November 2, 2012
Received: November 5, 2012

Dear Ms. Posca:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K123396

Device Name: i.flex by TCS

Indications For Use:

i.flex by TCS is a thermoplastic resin used for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2013.01.09 14:27:21 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: k123396